

REMARKS

Claims 24, 26, 30, 33, 35, 36, 38, 39, 41, and 42 are pending in the application. Applicants thank the Examiner for acknowledging the allowance of claims 24, 26, 30, 35, 38, and 41.

The rejection of claims 33, 36, 39, and 42 under 35 U.S.C. § 102(b) is standing. Claim 33 is currently amended, and the language is virtually identical to that of claim 33 prior to the amendment of February 18, 2005. Thus, no new matter has been added by this amendment. Applicants submit that the proposed amendment of claim 33 is sufficient to overcome the rejection of claims 33, 36, 39, and 42.

INTERVIEW SUMMARY

Applicants thank the Examiner for the courtesies extended in the telephone interview of October 7, 2005. In the interview, the undersigned and the Examiner discussed that the correct copy of Maniatis et al., *Molecular Cloning (A Laboratory Manual)*, Cold Spring Harbor Laboratory (1982) had not yet been submitted to the Examiner. Certain discrepancies between the specific hybridization conditions disclosed in the previously pending claims and those disclosed in Maniatis and in Example 5 of the current specification were also discussed.

AMENDMENTS TO THE SPECIFICATION

I. **Priority Claim**

Applicants have amended the first paragraph of the specification to reflect the correct priority claim. Specifically, Applicants have removed any claim to priority from applications filed prior to April 8, 1988. Accordingly, the effective filing date of this

application should now be April 8, 1988, and the pending claims are all entitled to this priority date.

II. Hybridization Conditions

Applicants have amended the paragraph beginning at page 7, line 35, to insert the hybridization conditions disclosed in Maniatis et al., *Molecular Cloning (A Laboratory Manual)*, Cold Spring Harbor Laboratory (1982) at pages 387 to 389 ("Maniatis"), cited in the application as filed. A copy of these pages is enclosed to demonstrate that these are the only hybridization conditions disclosed in those pages of the Maniatis reference manual. Applicants also include an affidavit executed by the undersigned stating that the amendatory material consists of the same material incorporated by reference to Maniatis. See *Manual of Patent Examining Procedure*, § 608.01(p). Although Applicants do not concede that this information is "essential" because one of skill in the art would readily understand the term "stringent hybridization conditions" as described in Maniatis, in order to expedite prosecution of this application, Applicants have amended the specification to incorporate this specifically referenced material.

REJECTION UNDER 35 U.S.C. § 102

Claims 33, 36, 39, and 42 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Wozney, *Science* 242(4885):1528-1534 (1988) ("Wozney"). The Examiner contends that Applicants are not entitled to claim priority to U.S. Serial No. 07/179,100 ("100 application"; now U.S. Patent No. 5,013,649), filed April 8, 1988, alleging that the hybridization conditions described in the claims are not disclosed in the '100 application, or in any later-filed application.

I. The Amended Claims

Applicants have amended claim 33 to remove the specific hybridization conditions from the claims, and have replaced this language with the language “stringent hybridization conditions.” Applicants had inserted the specific conditions in the claims after the Examiner indicated that this amendment would help overcome a rejection under 35 U.S.C. § 112, second paragraph (O.A. of 11/19/04; p.3). However, after discussing this claim at length with the Examiner during the interview of October 7, 2005, and after a review of PTO Examination Guidelines, Applicants have concluded that the term “stringent hybridization conditions” sufficiently defines the invention to comply with 35 U.S.C. § 112, second paragraph.

Specifically, the claim term “stringent hybridization conditions” is described in the current specification (page 8, lines 3-9) and the '100 application (page 5, lines 6-15) as being those conditions disclosed in Maniatis et al., *Molecular Cloning (A Laboratory Manual)*, Cold Spring Harbor Laboratory (1982), pages 387 to 389. The relevant pages of Maniatis provide a specific protocol for DNA hybridization with the following conditions—which Applicants specifically define as stringent conditions in the specification:

- (1) prehybridization of a filter for 2-4 hours at 68°C in prehybridization solution (6X SSC, 5X Denhardt's solution, 100 µg/ml denatured salmon sperm DNA);
- (2) hybridization for either 3-4 hours (cloned DNA) or 12-16 hours (total eukaryotic DNA) at 68°C in hybridization solution (6X SSC, 0.01M EDTA, 0.5% SDS, 100 µg/ml denatured salmon sperm DNA, labelled DNA probe);

- (3) wash at at 68°C with 2X SSC and 0.5% SDS, then 2X SSC and 0.1% SDS, then 0.1X SSC and 0.5% SDS.

As discussed above, these conditions have now been inserted into the specification.

These conditions were well known as of the earliest priority date of this application (April 8, 1988), evidenced in part by the fact that the referenced version of Maniatis was published in 1982, six years before the filing date of the '100 application. It is incontrovertible that Maniatis was (and still is) a ubiquitous laboratory reference manual and a primary source for DNA hybridization protocols such as the one described above. Thus, by referencing Maniatis, the application is describing to one of ordinary skill in the art the exact definition of the claimed stringent hybridization conditions.

II. The claims are adequately described in the specification of the earliest priority document

The basis of the Examiner's rejection under 35 U.S.C. § 102(b) is the contention that the claims are not adequately described in the '100 application, and thus, Applicants are not entitled to claim priority to the April 8, 1988 filing date of that application. The written description requirement serves to demonstrate that the applicant was in possession of the invention that is claimed. *In re Barker*, 559 F.2d 588, 592 n.4 (CCPA 1977) (the goal of the written description requirement is "to clearly convey the information that an applicant has invented the subject matter which is claimed"). Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information that is well known in the art need not be described

in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

In the instant specification, applicants have referred to an established protocol in an extremely well-known laboratory manual to describe the conditions used to isolate sequences that hybridize to the complement of the sequence of Figure 2. Thus, the hybridization conditions are “well known in the art,” as defined by *Hybritech*. By reference to precise hybridization conditions disclosed in Maniatis, the application clearly defines the term “stringent hybridization conditions,” and demonstrates possession of those nucleotide sequences that would hybridize to the sequence of Figure 2.

This conclusion is supported by the holding in *Vas-Cath*, which states that if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, then the adequate description requirement is met, even if every nuance of the claims is not explicitly described in the specification. *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Because Maniatis is such a well-known reference manual, one of skill in the art would understand that reference to this manual adequately described the conditions of the Maniatis hybridization protocol. Accordingly, Applicants submit that the claimed nucleotide sequences are described in the earliest priority document (the '100 application), and in every subsequent application filed up to the current specification, simply by the reference to the stringent hybridization conditions disclosed in Maniatis.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that Wozney, published in December, 1988, after the April 8, 1988 filing date of the '100 application, is not prior art to this application and the rejection under 35 U.S.C. § 102(b) should be withdrawn. Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any additional extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: November 16, 2005

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Attachments:

- Maniatis et al., Molecular Cloning (A Laboratory Manual), Cold Spring Harbor Laboratory (1982), pages 387-389;
- United States Application Serial No. 07/179,100: and
- Affidavit under M.P.E.P § 608.01(p).

CERTIFICATE UNDER 37 CFR § 1.10 OF
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